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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/596,086**

Applicant(s)  
**BIEDERMANN et al.**

Examiner  
**Brenda Coleman**

Art Unit  
**1624**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 22, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 55-77 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-58 and 60-77 is/are rejected.
- 7) ☒ Claim(s) 59 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

Claims 55-77 are pending in the application.

This action is in response to applicants' amendment filed May 22, 2003. Claims 32-54 have been canceled and claims 55-77 are newly added.

#### ***Response to Amendment***

Applicants' arguments filed May 22, 2003 have been fully considered with the following effect:

1. With regards to the objection to the Information Disclosure Statement the applicants failed to comment.

The information disclosure statement filed January 4, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the first citation under the heading OTHER DOCUMENTS is **incomplete and not in the English language**. The reference to this article fails to include the Arthur, title, date, volume, number, pertinent pages, etc. The article is also in a language which the examiner cannot understand and hence cannot be considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

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It is also noted that there are three Chemical Abstracts listed under the heading OTHER DOCUMENTS where there is no indication what the chemical abstract number is. For example, the first Chemical Abstract listed is Vol. 124, No. 13, 1996, but there are citations on the page provided, i.e. 124:173007q, 124:173008r, 124:173009s, 124:173010k, 124:173011m, 124:173012n, 124:173013p, 124:173014q, 124:173015r and part of 124:173016s. It is also noted that the applicants have recited a Rote Liste, however, it is not known what is meant by the Rote Liste, 1997 which is the last citation under the heading OTHER DOCUMENTS.

2. With regards to the objection to the abstract of the disclosure, the applicants failed to comment.

The abstract of the disclosure is objected to because the content of the abstract is of different scope than the claims. Correction is required. See MPEP § 608.01(b).

The abstract submitted by the applicants with this amendment does not appear to be amended. The formula still contains a variable which is not defined with respect to the invention, i.e. E.

3. The applicants amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 8-31, labeled paragraph 4) in the last office action, which is hereby **withdrawn**.

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4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 5 a), l) and w) in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 5 h) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

h) The applicants stated that the "dependent claims have been amended to make the preamble consistent". However, claim 58 still states "[t]he compounds".

Claim 58 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

5. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 6 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. While the proviso at the end of claim 55 may exclude the species which those conditions are met, it does not exclude the species if  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-\text{CH}=\text{CH}-$ ; D is  $-(\text{CH}_2)_5-\text{N}(\text{CH}_2\text{CH}_3)-$ ; and G is  $-\text{CH}_2-\text{Ph}$ . It is noted that this is the same species, however, the varying degree of each of the variables overlap as far as definitions are concerned.

Claims 55-57, 60 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishihara et al., Chem. Pharm Bull. For reasons of record and stated above.

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6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 7 in the last office action, which is hereby **withdrawn**.

7. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 8 a), b), d), g), h), i), j), k), l), m), n), o), p), q), r), s), t), u), v), w), x), y), z), aa), ab), ac), ad), ae), af), ag), ah), ai), aj), ak), al), am), an), ao), ap), aq), ar), as), at), au), aw), ay), bb), bc), bd) and bg) in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 8 c), e), f), av), ax), az), ba), be), bf), bh) and bi) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- c) The applicants stated that the claims have been rewritten as "R<sup>7</sup> has the same meaning as R<sup>6</sup>". However, claim 72 still states "R<sup>7</sup> has the same as R<sup>6</sup>". Has the same what? (See page 48, line 20)
- e) The applicants stated that the claims have been amended such that the definition of G<sup>4</sup> has "added indication to point of attachment". However, the definition of G<sup>4</sup> in claim 73 has not been amended. (See page 58, lines 4 and 6)
- f) The applicants stated that the claims have been amended such that the "point of attachment and groups have been defined". However, the definition of the structural element D-G states that the "group -NR<sup>8</sup>R<sup>9</sup>" can have the above

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meanings. However, there is no definition for the **group** -NR<sup>8</sup>R<sup>9</sup>. (See claim 56, page 12, line 16; claim 57, page 17, line 17; claim 60, page 27, line 9; claim 70, page 36, line 3; claim 71, page 43, line 3; claim 72, page 50, line 10; claim 73, page 58, line 9; claim 75, page 70, line 1; claim 76, page 76, line 10; and claim 77, page 81, line 14)

- av) The applicants stated that “support for the dosage amounts is claimed at page 130 of the specification”. However, claim 69 is dependent on claim 68 which is limited to 1 to 10 mg. (See page 30)
- ax) The applicants stated that they “added definitions”. However, the definition of m still does not appear in the claim. (See claim 73, page 53, lines 5 and 6; page 57, lines 12, 13, 18 and 19; and page 58, lines 4, 8 and 11)
- az) The applicants stated that they “changed =CR<sup>8</sup>R<sup>9</sup> to =CR<sup>9</sup>R<sup>10</sup>. However, there is no moiety =CR<sup>9</sup>R<sup>10</sup> in the claim. (See claim 73, page 59, line 13)
- ba) The applicants stated that they “added definitions of variables”. However, the definition of n still does not appear in the claim. (See claim 74, page 61, line 1)
- be) The applicants stated that they “added definitions of variables”. However, the definition of m still does not appear in the claim. (See claim 75, page 65, line 8; page 69, lines 19 and 23; and page 70, line 3)

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- bf) The applicants stated that they “added definitions”. However, the definition of R<sup>11</sup> still does not appear in the claim. (See claim 75, page 66, line 2; pages 69, lines 19 and 21; page 70, lines 1, 8 and 9; page 71, line 6)
- bh) The applicants stated that they “changed =CR<sup>8</sup>R<sup>9</sup> to +CR<sup>9</sup>R<sup>10</sup>. However, there is no moiety [=]CR<sup>9</sup>R<sup>10</sup> in the claim. (See claim 75, page 71, line 7) With regards to claim 76 the moiety =CR<sup>8</sup>R<sup>9</sup> has not been changed to =CR<sup>9</sup>R<sup>10</sup>. (See claim 76, page 76, line 14)
- bi) The applicants stated that they “added indication of point of attachment” to the definition of G. However, this is not so. (See claim 77, page 81, line 11)

Claims 56-58, 60, 69-77 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

In view of the amendment dated May 22, 2003, the following new grounds of rejection apply:.

***Claim Rejections - 35 USC § 112***

The following is as a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain as a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.



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8. Claim 70 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the preamble where the specific tumors are listed includes "combinations thereof" which is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

9. Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of L includes "mixtures thereof" which is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 55-58, 60-69 and 72-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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- a) Claim 55 is vague and indefinite in that it is not known what is meant by CH=CH- in the definition of A of the proviso. It is believed that the applicants intended -CH=CH-. (See page 8)
- b) Claim 56 is vague and indefinite in that it is not known what is meant by the definition of R<sup>8</sup> which is selected from the group consisting of. It is believed that the applicants intended consisting of. (See page 11)
- c) Claim 57 is vague and indefinite in that it is not known what is meant by the definition of R<sup>8</sup> which is selected from the group consisting of. It is believed that the applicants intended consisting of. (See page 16)
- d) Claim 57 recites the limitation "aromatic ring systems" in R<sup>3</sup>. There is insufficient antecedent basis for this limitation in the claim. (See page 19, line 2)
- e) Claim 58 is vague and indefinite in that it is not known what is meant by the moiety naphthylmethyaminocarbonylamino and biphenylylaminocarbonylamino in the definition of G. (See page 21, lines 3 and 4)
- f) Claims 60-69 are vague and indefinite in that it is not known what is meant by CH=CH- in the definition of A of the proviso. It is believed that the applicants intended -CH=CH-. (See page 29)
- g) Claim 72 is vague and indefinite in that it is not known what is meant by CH=CH- in the definition of A of the proviso. It is believed that the applicants intended -CH=CH-. (See page 52)

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- h) Claim 73 is vague and indefinite in that it is not known what is meant by the definition of L which includes a reactive **h**ologenated derivatives of an alcohol.  
(See page 53)
- i) Claim 73 recites the limitation " $=CR^8R^9$ " in the definition of  $G^2$ . There is insufficient antecedent basis for this limitation in the claim. However, there is no variable  $G^2$  within the claim. (See page 57, lines 9-11)
- j) Claim 73 is vague and indefinite in that it is not known what is meant by the second occurrence of the definition of  $G^3$  and n on page 57. (See page 57, lines 12-15 and 18-21)
- k) Claim 73 is vague and indefinite in that it is not known what is meant by the definition of  $X^1$  with respect to the variable  $G^6$  when there is no variable  $X^1$  in  $G^6$ .  
(See page 59)
- l) Claim 74 is vague and indefinite in that there is no definition for the variable  $R^{11}$ .  
(See page 61, line 2)
- m) Claim 74 is vague and indefinite in that it is not known what is meant by the definition of N, since there is no variable N in the claim. (See page 64)
- n) Claim 75 is vague and indefinite in that it is not known what is meant by the definition of  $R^8$  which is selected from the group consisting of. It is believed that the applicants intended consisting of. (See page 68)

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- o) Claim 76 is vague and indefinite in that there is no definition for the variable X in the claim. (See page 72)
- p) Claim 76 is vague and indefinite in that it is not known what is meant by the definition of  $R^8$  which is selected from the group consisting of. It is believed that the applicants intended consisting of. (See page 75)
- q) Claim 76 is vague and indefinite in that it is not known what is meant by the definition of  $R^{10}$  since there is no variable in the claim. (See page 76, lines 5, 10 and 14)
- r) Claim 76 is vague and indefinite in that it is not known what is meant by the definition of G which does not indicate the point of attachment of the moiety. (See page 76)
- s) Claim 76 is vague and indefinite in that there is no definition for the variable  $R^{11}$ . (See page 76, lines 7, 10 and 14)
- t) Claim 76 is vague and indefinite in that it is not known what is meant by the definition of m, since there is no variable in the claim. (See page 76, line 9)
- u) Claim 77 is vague and indefinite in that it is not known what is meant by the definition of  $R^8$  which is selected from the group consisting of. It is believed that the applicants intended consisting of. (See page 80)

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- v) Claim 77 is vague and indefinite in that it is not known what is meant by the definition of  $R^{10}$  since there is no variable in the claim. (See page 81, lines 9 and 14)
- w) Claim 77 is vague and indefinite in that there is no definition for the variable  $R^{11}$ . (See page 81, lines 11 and 14)
- x) Claim 77 is vague and indefinite in that it is not known what is meant by the definition of  $m$ , since there is no variable in the claim. (See page 81, line 13)

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

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Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Nadzan et al., U.S. Patent No. 4,971,978. Nadzan teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-\text{CH}=\text{CH}-$ ; D is  $-\text{CH}(\text{C}(\text{O})-\text{N}(\text{C}_3\text{H}_{11})_2)-\text{CH}_2-\text{CH}_2-\text{C}(\text{O})-$ ; and G is  $-\text{O}-\text{CH}_2-\text{Ph}$ . See the CAPLUS printout of RN 122667-88-3 herein provided.

12. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Spatz et al., U.S. Patent No. 4,892,952. Spatz teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is  $-\text{CH}_2-\text{CH}_2-\text{CH}_3$ ; A is  $-\text{CH}_2-$  or  $-\text{CH}=\text{CH}-$ ; D is  $-\text{CH}_2-\text{CH}_2-\text{O}-$ ; and G is 2,4,6-trichlorophenyl. See the CAPLUS printout of RN 99914-35-9 and 127657-28-7 herein provided.

13. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Goto et al., JP Patent No. 02-212459. Goto teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-\text{CH}=\text{CH}-$ ; D is  $-(\text{CH}_2)_5-\text{N}(\text{CH}_2\text{CH}_3)_2-$ ; and G is  $-\text{CH}_2-\text{Ph}$ . See the CAPLUS printout of RN 131334-22-0 herein provided.

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14. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al., J. Enzyme Inhib. Saito teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-O-(CH_2)_3-$ ; D is  $-CH(CO_2H)-CH_2-CH_2-$ ; and G is phenyl. See the CAPLUS printout of RN 136768-47-3 herein provided.
15. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Koenig et al., U.S. Patent No. Koenig teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-CH_2-CH(NH_2)-$ ; D is  $-CH(CH_2-OBu-t)-C(O)-NH-CH(CO_2Bu-t)-$ ; and G is  $-CH_2-(4\text{-tertbutoxyphenyl})$ . See the CAPLUS printout of RN 142994-22-7 herein provided.
16. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al., Pharm. Res. Hashimoto teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-CH_2-CH_2-$  or  $-CH_2-$ ; D is  $-CH(CO_2H)-(CH_2)-$ ; and G is  $-Ph$ . See the CAPLUS printout of RN 139522-04-6 and 160855-85-6 herein provided.
17. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Kukkola et al., Bioorg. Med. Chem. Lett. Kukkola teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-(CH_2)_2-$  or  $-CH_2-$ ; D is

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-CH(CH<sub>2</sub>SH)-CH<sub>2</sub>-; and G is phenyl. See the CAPLUS printout of RN 176253-11-5 and 176253-12-6 herein provided.

18. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh et al., WO 96/16981. Itoh teaches the compounds and compositions of the instant invention where R<sup>1</sup> is H; R<sup>2</sup> is H; R<sup>3</sup> is H; A is -CH<sub>2</sub>-CH(NH<sub>2</sub>)-; D is -CH(CH<sub>2</sub>-Ph)-C(O)-N(CH<sub>3</sub>)-; and G is -CH<sub>2</sub>-Ph. See the CAPLUS printout of RN 179876-17-6 herein provided.

19. Claims 55, 60, 70, 71 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al., WO 96/22966. Adams teaches the compounds, compositions and method of use of the compounds of the instant invention where R<sup>1</sup> is H; R<sup>2</sup> is H; R<sup>3</sup> is H; A is -CH<sub>2</sub>-; D is -CH(i-Bu)-CO-NH-CH(CH<sub>2</sub>-CO<sub>2</sub>H)-; and G is phenyl. See the CAPLUS printout of RN 181519-80-2 herein provided.

20. Claims 55 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al., J. Am. Chem. Soc. Myers teaches the compounds of the instant invention where R<sup>1</sup> is H; R<sup>2</sup> is H; R<sup>3</sup> is CH<sub>3</sub>; A is -CH<sub>2</sub>-; D is -CH(CH<sub>3</sub>)-CH(OH)-; and G is -Ph. See the CAPLUS printout of RN 192060-37-0 herein provided.

21. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Fujisawa et al., WO 97/41104. Fujisawa teaches the compounds and compositions of the instant invention where R<sup>1</sup> is -C(O)-OEt; R<sup>2</sup> is H; R<sup>3</sup> is H; A is -CH=CH; D is -CH<sub>2</sub>-C(O)-



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N(CH<sub>3</sub>)-; and G is 2,4-dichloro-3-(hydroxymethyl)phenyl. See the CAPLUS printout of RN 199106-68-8 herein provided.

22. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(a) as being anticipated by Audia et al., WO 98/22494. Audia teaches the compounds and compositions of the instant invention where R<sup>1</sup> is H; R<sup>2</sup> is H; R<sup>3</sup> is H; A is -CH<sub>2</sub>-; D is -CH(CH<sub>3</sub>)-C(O)-NH-CH(CO-O-CH<sub>3</sub>)-; and G is -CH<sub>2</sub>-Ph. See the CAPLUS printout of RN 208255-71-4 herein provided.

23. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(a) as being anticipated by Santangelo et al., U.S. Patent No. 5,760,241. Santangelo teaches the compounds and compositions of the instant invention where R<sup>1</sup> is H; R<sup>2</sup> is H; R<sup>3</sup> is H; A is -CH<sub>2</sub>-CH(CH<sub>2</sub>SH)-; D is -CH(CO<sub>2</sub>H)-CH<sub>2</sub>-; and G is biphenyl. See the CAPLUS printout of RN 181282-21-3 and 181282-23-5 herein provided.

24. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(a) as being anticipated by Hayes et al., WO 98/34111. Hayes teaches the compounds and compositions of the instant invention where R<sup>1</sup> is H; R<sup>2</sup> is H; R<sup>3</sup> is H; A is -CH=CH-; D is -CH(CONH<sub>2</sub>)-CH<sub>2</sub>-; and G is -4-nitrophenyl. See the CAPLUS printout of RN 211376-05-5 herein provided.

25. Claims 55 and claims dependent thereon are rejected under 35 U.S.C. 102(e) as being anticipated by Palmer et al., U.S. Patent No. 5,977,302. Palmer teaches the compounds of the

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instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-\text{CH}_2-\text{CH}(\text{NH}_2)-$ ; D is  $-\text{CH}(\text{CH}_2\text{OH})-\text{CO}-$ ; and G is  $-\text{CH}_2\text{-phenyl}$ . See the CAPLUS printout of RN 225931-70-4 herein provided.

26. Claims 55, 60, 71 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Sham et al., WO 97/21685. Sham teaches the compounds, compositions and method of use of the compounds of the instant invention where  $R^1$  is methyl;  $R^2$  is methyl;  $R^3$  is H; A is  $-\text{O}-\text{CH}_2-$ ; D is  $-\text{CH}(\text{CH}_2\text{Ph})-\text{CH}(\text{OH})-\text{CH}_2-\text{CH}(\text{NH}-\text{CO}-\text{OBu-t})-$  or  $-\text{CH}(\text{CH}_2\text{Ph})-\text{CH}(\text{OH})-\text{CH}_2-\text{CH}(\text{NH}_2)-$ ; and G is  $-\text{CH}_2\text{-Ph}$ . See the CAPLUS printout of RN 192725-66-9 and 192725-67-0 herein provided.

27. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Abelman et al., WO 96/19493. Abelman teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is methyl; A is  $-\text{CH}_2-\text{CH}(\text{NH}_2)-$ ; D is  $-\text{CH}_2-\text{CO}-\text{O}-\text{CH}_2-$ ; and G is phenyl. See the CAPLUS printout of RN 180312-87-2 herein provided.

28. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(e) as being anticipated by Hu et al., U.S. Patent No. 6,166,052. Sham teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-\text{CH}_2-\text{CH}(\text{NH}-\text{CH}_2-\text{CH}_2-\text{CH}(\text{CH}_3)_2)-$ ,  $-\text{CH}_2-\text{CH}(\text{N}(\text{Me})-(\text{CH}_2-\text{CH}_2-\text{CH}(\text{CH}_3)_2))-$ ,  $-\text{CH}_2-\text{CH}(\text{N}(\text{Me})(i\text{-Bu}))-$ ,  $-\text{CH}_2-\text{CH}(\text{N}(\text{Me})-\text{CH}_2-\text{CH}_2-\text{CH}(\text{CH}_3)_2)-$ , and  $-\text{CH}_2-\text{CH}(\text{NH}_2)-$ ; D is  $-\text{CH}(\text{CO}-\text{NH-t-Bu})-\text{CH}_2-$ ; and G is  $-(4\text{-benzyloxyphenyl})$ ,  $-(4\text{-(3,3-dimethylbutylphenyl)})$ . See the CAPLUS printout of RN 277753-

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27-2, 314081-68-0, 314081-70-4, 314081-72-6, 314081-80-6, 314081-91-9, 314082-16-1, 314082-08-1 and 314082-17-2 herein provided.

29. Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al., U.S. Patent No. 6,191,166. Wu teaches the compounds and compositions of the instant invention where  $R^1$  is H;  $R^2$  is H;  $R^3$  is H; A is  $-\text{CH}_2-$ ; D is  $-\text{CH}(\text{CH}_3)-\text{CO}-\text{NH}-\text{CH}(\text{CO}_2\text{Me})-$ ; and G is  $-\text{CH}_2-\text{Ph}$ . See the CAPLUS printout of RN 208255-71-4 herein provided.

#### ***Claim Objections***

30. Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

31. Applicants' attention is directed to U.S. Patent No. 6,313,153, which while not competent as a reference against the instant claims, claims subject matter that is similar and/or identical to that claimed herein. Two patents cannot issue on the same subject matter, unless applicants can demonstrate that the claims are patentably distinct from the claims of this US patent, the only way to overcome this patent is by way of Interference proceedings or removal of the conflicting subject matter. See MPEP 2306.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman  
Primary Examiner AU 1624  
August 8, 2003